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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,615	02/20/2004	Salim Yusuf	57151-CON(46453)	7220

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EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,615

Applicant(s)

YUSUF, SALIM

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-20-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-19 are presented for examination.

Applicant's preliminary amendment, information disclosure statement and drawings filed February 20, 2004 have been received and entered.

Applicant's election filed November 19, 2004 in response to the restriction requirement of October 26, 2004 has been received and entered. The applicant elected the invention described in claims 1-11 (Group I) with traverse.

Applicant's traverse of the restriction requirement is not deemed persuasive for reasons set forth in the Office action dated October 26, 2004; therefore, the restriction requirement is hereby made Final.

Claims 12-19 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant's oath and/or declaration does not claim priority under 35 USC 119(e) as stated in his specification on page 1, line 9.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 of copending Application No. 10/492,919.

Both applications are claiming:

A method of reducing diabetes in patient(s) who is at risk for developing diabetes, said method comprising administering to a patient, who is at risk for developing diabetes, an effective amount of an angiotension converting enzyme inhibitor for sufficient period of time to prevent the development of diabetes such patient(s). Note the diabetes is Type 2 Diabetes, and the angiotensin converting enzyme inhibitor is ramipril.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-4 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yusuf et al., "Ramipril and the development of diabetes", Jama the Journal of the American Medical Association, Vol. 286, No.15, (2001), pp. 1882-1885 of PTO-1449 (CI).

Yusuf et al. teach the effectiveness of ramipril, an angiotensin converting enzyme inhibitor (ACE) in preventing diabetes among high-risk persons. Note the type of diabetes that is treated is Type 2 diabetes and the patient(s) used in the experiment were other than 55 years without known diabetes, but with vascular disease. Note the dosage of ramipril administered is up to 10 mg per day. As to the B-cell function in such patient(s) is slowed or reversed; islet blood flow is increased; pancreatic B-cell perfusion is increased; insulin resistance in skeletal muscles is reduced; insulin-mediated glucose disposal is increased; and insulin-mediated glucose uptake by skeletal muscle is increased, a product of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. If the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). In the instant case, the aforesaid B-cell function in such patient(s) is slowed or reversed; islet blood flow is

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increased; pancreatic B-cell perfusion is increased; insulin resistance in skeletal muscles is reduced; insulin-mediated glucose disposal is increased; and insulin-mediated glucose uptake by skeletal muscle is increased is anticipated by Yusuf et al., because the reference teaches the identical ACE inhibitor, ramipril, of the instant claims.

Therefore, claims 1-11 are not allowed.

The remaining reference listed on the enclosed PTO-892 is cited to show the stated of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
August 15, 2005